

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/011381

International filing date (day/month/year)
01.04.2005

Priority date (day/month/year)
01.04.2004

International Patent Classification (IPC) or both national classification and IPC
A61K31/409, A61P35/00, A61P35/04, A61P43/00

Applicant
CASE WESTERN RESERVE UNIVERSITY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 12-24

because:

- ☒ the said international application, or the said claims Nos. 12-24 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/011381

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5, 6, 8-11, 18, 19, 21-24, 28, 29, 31, 32
	No: Claims	1-4, 7, 12-17, 20, 25-27, 30, 33
Inventive step (IS)	Yes: Claims	
	No: Claims	1-33
Industrial applicability (IA)	Yes: Claims	1-11,25-33
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Cited Documents

- D1: WO 02/096913
- D2: EP-A-0 633 024
- D3: EP-A-0 720 853
- D4: WO 92/01753
- D5: US-A-5 358 940
- D6: WO 95/06688
- D7: WO 99/23882
- D8: VOROZHTSOV, G N ET AL: "Phosphonylmethyl phthalocyanine derivatives in preparations for photodynamic therapy" CHEMICAL ABSTRACTS 2002, vol. 136, abstract no. 183942.
- D9: WO 03/037902
- D10: WAINWRIGHT, M: "Local treatment of viral disease using photodynamic therapy" INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS 2003, 21, 510-520.

Section III

1. Claims 12-24 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art. 34(4)(a)(I) PCT).

Section V

2. Claims 1-4, 7, 12-17, 20, 25-27, 30 and 33 do not meet the requirements of Art. 33(2) PCT because compositions falling within the scope of the present claims are known in the prior art for use in methods of treatment also falling within the scope of the present application. See documents D1-D4, D6, D7 and D8.
3. The novel aspects of the claimed subject-matter cannot be seen as meeting the requirements of Art. 33(3) PCT.

It is clear from the cited prior art that compositions claimed in the present application are useful in the treatment of tumours. Furthermore, topical administration is presented as being a viable, if not preferred, mode of administration (see D2, page 2, lines 8-18 and D3, page 2, lines 5-24).

Moreover, the use of novel salts of known pharmaceuticals cannot be seen as being inventive unless their use results in an advantageous or unexpected effect

not derivable from the prior art.

4. Notwithstanding the above objections, the claimed subject-matter does not meet the requirements of Art. 33(3) PCT over its whole scope.

It is clear from D3 (page 2, lines 20-24) that not all topical formulations of (at least) zinc phthalocyanines are effective in providing significant skin penetration and hence being of use in PDT.

Moreover, the Applicant has only provided data to cover a very small sub-set of the range of compounds claimed.

A reasonable doubt that the underlying technical problem is solved over the whole scope of the claims therefore exists and an inventive step cannot be recognised for the present claims.

5. For the assessment of the present claims 12-24 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Section VIII

6. Claim 16 is unclear because it refers to "a pharmaceutical composition of claim 14", whereas claim 14 is directed to a method of treatment.

Similar objections apply to claim 23 in respect of its dependency upon claim 22.